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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,665	11/17/2003	Mark Selby	PP01635.007	5235

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,665	SELBY ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *1-33,38-41,46-65,70-76 and 78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-37, 42-45, 66-69, and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-17-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-33, 38-41, 46-65, 70-76, and 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on January 26, and March 10, 2005.

2. Currently, claims 34-37, 42-45, 66-69, and 77 are pending and under consideration.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on November 17, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

4. The following reference is in a foreign language accompanied by an English abstract. Due to this, the reference has been examined only to the extent of the disclosure in the abstract.

EP 0 201 416.

Oath/Declaration

5. The Oath/Declaration submitted on November 17, 2003 is accepted because the Declaration names the inventors, and contains the attorney docket number that was on the specification of the parent application as filed. These two means of identification are among the acceptable minimum modes of identification as indicated in MPEP § 602.

Specification

6. The disclosure is objected to because of the following informalities: the specification indicates on page 5 (description of Figures 4A and 4B) that the E2 coding sequence in SEQ ID NO: 6 begins at base 1997. The first three codons of this sequence encode the amino acid sequence Met-Asp-Ala. However, the specification also indicates that the E2 protein sequence begins at residue 384 of the HCV polyprotein (page 22), which based on the disclosure of Choo et al. (PNAS 88:2451-55) would have the sequence Glu-Thr-His. It is further noted that these three residues are encoded beginning with base 2067 of SEQ ID NO: 6. From these various teachings, it is unclear if, as the specification asserts on page 5, the E2 coding sequence begins at residue 1997; or if the E2 coding sequence actually begins at residue 2067, as is indicated by a comparison of the teachings on page 22 with the sequence disclosures in Choo and Figure 4. Further, a comparison of the coding sequence of bases 1992-2060 with the coding sequence for a human plasminogen activator sequence (Genbank E01163, bases 87-155) demonstrates that the sequence is identical to a portion of the human plasminogen activator leader sequence. It is noted that this leader sequence is indicated to be included in the pCMVII plasmid sequence described on page 26 of the present specification. Thus, it appears that the coding sequence for the E2 protein begins not at base 1992, but at base 2067.

Clarification of these disparate teachings is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 34, 35, 37, 42, 45, 66, 67, and 69 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. These claims are directed, in part, to nucleic acids which encode amino acid sequences with homology to an indicated fragment of HCV E2 proteins of at least about 80%. However, the application neither provides a utility for such variant polypeptides other than those asserted for the E2 fragments themselves, nor describes such polypeptides in a manner limiting them to embodiments sharing at least one immunogenic epitope with the E2 proteins (i.e. able to induce an immunogenic response against HCV or an HCV antigen). Thus, the claims are drawn to a group of nucleic acids encoding any protein with up to about 20% variation from any HCV E2 protein fragment corresponding to residues 384-661 of HCV-1, without regard for the polypeptides ability to induce an immune response against HCV. Because the ability of a polypeptide to induce an immune response against a specific pathogen is dependent on its sequence, and because there is no requirement in the claims that the variants of at least about 80% homology be able to induce an immune response against HCV, the application is claiming polypeptides for which there is no apparent utility. I.e., no utility has been asserted for immunogenic sequences of at least about 80% identity with the indicated E2 fragment which are not able to induce an immune response against HCV. The claims are therefore rejected as including embodiments for which no specific and substantial utility has been provided.

Claims 34, 35, 37, 42, 45, 66, 67, and 69 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Because those in the art would not know how to use any protein with 80% identity to SEQ ID NO: 6 absent such protein sharing at least one epitope with the included antigens, those in the art have not been enabled for the making and use of any nucleic acid encoding any fusion protein of at least about 80% identity to residues to an HCV E2 protein, or to bases 1992-3584 of SEQ ID NO: 6.

It is noted that, for the purposes of this rejection, claim 37 is interpreted as reading on a polynucleotide having at least about 80% sequence identity to SEQ ID NO: 6, and encoding an immunogenic sequence.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 37, 45, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on an indicated nucleic acid sequence or "an immunogenic sequence having at least about 80% sequence identity thereto." These claims read on nucleic acid sequences that are themselves immunogenic. However, from the language of the claims from which these claims depend, it would appear that the Applicant intended to

claim nucleic acid sequences encoding immunogenic polypeptides. Because it is unclear whether the Applicant intended the term "immunogenic" as a descriptor for the nucleic acid sequence itself, or the protein sequence encoded by the claimed nucleic acid, the claims are rejected for indefiniteness.

Clarification of the claim language is required.

For the purposes of this action, the claims are treated as though they required that the nucleic acids encode an immunogenic polypeptide, rather than requiring that the nucleic acids are themselves immunogenic.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 34-36, 42-44, and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Major et al. (J Virol 69: 5798-5805- of record in the Nov. 2003 IDS) in view of Michalak et al., (J Gen Virol 78: 2299-2306), and further in view of Valenzuela et al. (Bio/Technology 3: 323-26- also of record in the Nov. 2003 IDS). The claims read on nucleic acids encoding a fusion protein comprising a substantially complete S domain of HBsAg, and a polypeptide comprising residues 384-661 of an HCV polyprotein (corresponding to a region of the E2 envelope protein), and to vectors and immunogenic compositions

comprising such nucleic acids. Dependent claims 35, 43, and 67more specifically require that the E2 polypeptide is fused to the N-terminus of the S protein.

Major teaches the use of a nucleic acid encoding an E2 protein for DNA based vaccination against HCV. The reference teaches that nucleic acids wherein the E2 sequences are expressed to the N-terminus of the S sequence are efficiently expressed, and are effective at inducing anti-HCV responses, whereas DNA encoding only the E2 polypeptide was not. Page 5801 (paragraph entitled "(i) Anti-HCV Ab responses"). However, while the reference teaches the making and use of immunogenic compositions comprising a nucleic acid encoding an E2/S protein fusion, the reference does not teach or suggest the claimed embodiments, wherein the E2 polypeptide comprises residues 384-661.

Michalak describes the recombinant expression of truncated versions of the HCV E1 and E2 proteins. The reference teaches that a truncated form of the E2 protein comprising residues 370-661 (an E2 sequence comprising residues 384-661) was efficiently expressed and secreted in transformed cells (pages 2301), and that this protein represented the single truncated form of E2 to be recognized by an anti-E2 antibody that binds only to properly folded E2 polypeptides (page 2302). Thus, the reference teaches that this truncated form of E2 is both properly folded, and capable of expression and secretion from cells. The reference also suggests that this E2 polypeptide may be useful in anti-HCV vaccines, thereby suggesting the use of the protein in anti-HCV immunogenic compositions. Because the reference suggests that this polypeptide may be useful in anti-HCV vaccines, and indicates that the protein is efficiently expressed and secreted by recombinant host cells, it would have been obvious to those in the art to use this polypeptide as the E2 polypeptide in an anti-HCV composition such as that disclosed by Major.

The motivation to make this substitution is found in the combined teachings of Major (indicating that it is preferable to use antigen "presented in a more natural form," page 5798, right column), and Michalak (teaching that the E2 truncated at residue 661 is secreted in a properly folded version- thus mimicking, and being recognized by an antibody targeting, the wild-type E2 protein).

Those in the art would have had a reasonable expectation of success in the combination based on the teachings of Major, indicating the success in inducing anti-HCV responses using a similar fusion protein. Further, the Valenzuela et al. reference also demonstrated success in the expression of a fusion protein comprising the S protein and a herpes virus antigen of about 300 amino acids- i.e. a fusion protein with a similar length to that of the fusion that would result from the combination of Michalak and Major. Those in the art would therefore have had a reasonable expectation of success in the expression of a similar-sized chimer comprising a HCV sequence rather than a herpesviral antigen.

The teachings of Lee et al. (J Med Virol 50: 145-51- of record in the Nov. 2003 IDS), indicating unpredictability in the secretion of different fusions of HCV E2 fragments and HBsAg are noted. However, these teachings are not deemed to affect the reasonable expectation of success in the combination of Michalak and Major because the fusion proteins are Lee are different from those of Major. Lee teaches the formation of a fusion protein comprising an HBsAg wherein E2 peptides are inserted internally to the S protein sequence. Based on the success in Valenzuela and Major, fusing the E2 polypeptide to the N-terminus of the S protein is more predictable and certain that the insertion of the foreign sequence internally to the S protein.

14. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (U.S. 6,306,625), in view of Major, Michalak, and Valenzuela as applied to claims 34-36, 42-44, and 66-68 above. This claim reads on a cell line that expresses a virus-like particle comprising an HBsAg, and a chimeric antigen comprising an HBsAg linked to an HCV immunogenic polypeptide.

Jacobs teaches the use of HBsAg as a carrier molecule for other antigenic sequences, and teaches the fusion of such other sequences to the N-terminus of the S protein sequence. See e.g., columns 3-4, and column 9 lines 31-45. The reference also teaches cell lines comprising nucleic acids encoding such chimeric antigens, in combination with nucleic acids encoding only HBsAg, wherein the cells express HBsAg particles (i.e. virus-like particles formed from HBsAg and the chimeric antigens). Column 4, column 10. However, the reference does not teach or suggest embodiments wherein the antigen fused to HBsAg is a HCV antigen or is the HCV E2 protein.

The teachings of Major, Michalak, and Valenzuela have been described above. These references do teach the making of nucleic acids encoding a fusion of a truncated E2 protein and HBsAg. Further, the Valenzuela reference further teaches that the fusion proteins described therein (a fusion of HBsAg and another antigen of approximately the same size as the truncated E2 protein) formed virus-like particles upon expression. Thus, in combination with the teachings of Jacobs, this reference provides those in the art with a reasonable expectation of success in the making and use of virus-like particles comprising a truncated E2 antigen, wherein the particles are expressed from a host cell comprising nucleic acids encoding both the chimeric, and the wild-type HBsAg proteins. The combination of Jacobs in view of Major, Michalak, and Valenzuela therefore render claim 77 obvious.

15. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Major, Michalak, and Valenzuela as applied to claim 77 above, and further in view of the teachings of and GenBank Accession Numbers X02763, and M62321. Claim 37 reads on a nucleic acid as indicated above, wherein the nucleic acid comprises bases 1992-3584 of SEQ ID NO: 6, or an immunogenic sequence with 80% identity thereto. This sequence comprises just under 1600 nucleic acid bases. Thus, the claims permit variation from this sequence by up to about 320 bases (20% of 1600).

The teachings of Jacobs in view of Major, Michalak, and Valenzuela have been described above. However, the Jacobs does not specify HCV as the antigen to which HBsAg is fused, and the other references do not teach the sequence of the HBsAg E2 proteins incorporated into the fusions. Because it is not clear from these references what the sequences of the resulting nucleic acid fusion coding sequence would be, these teachings do not alone render claim 37 obvious.

The sequence of X02763 bases 1564-2241 is identical to the sequence of bases 2907-3583 of SEQ ID NO: 6. This sequence is the coding sequence for a known HBsAg. It would therefore have been obvious for those in the art to use this sequence as the coding sequence for the HBsAg portion of the fusion protein. The sequence of M62321 bases 1491-2324 varies from the sequence of residues 2067-2900 of SEQ ID NO: 6 (coding for a portion of the HCV E2 protein) by one amino acid. Because this sequence represents a known E2 protein sequence, it would have been obvious to those in the art to use this sequence as the E2 sequence in the fusion protein. Combining the E2 and HBsAg sequences of GenBank Accessions M62321 and X02763, as suggested by the teachings of Jacobs in view of the previously cited references, those in the art

would have achieved a nucleic acid that varied from bases 1992-3584 of SEQ ID NO: 6 by no more than 80 residues. These differences would be in the N-terminal 75 bases of the E2 coding sequence, the lack of the six bases of 2901-2906 of SEQ ID NO: 6, and a variation from the HBsAg sequence by one base. Because the combination of these references would result in a protein with at least 80% identity to bases 1992-3584 of SEQ ID NO: 6, the combined teachings of these references render the claimed invention obvious. Those in the art would have had a reasonable expectation of success in the combination based on the teachings of Jacobs, Major, and Valenzuela as described above.

16. Claims 45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of the teachings of Major, Michalak, Valenzuela, and GenBank Accessions M62321 and X02763 as applied to claim 37 above (cumulatively, Jacobs etc.), and further in view of Selby et al. (U.S. 6,096,505), Chapman et al. (Nuc Acids Res 19: 3979-86), and Hartikka et al. (Hum Gene Ther 7: 1205-17). These claims are drawn to vectors comprising the sequence of SEQ ID NO: 6, or sequences with at least 80% identity thereto, and immunogenic compositions comprising such. SEQ ID NO: 6 is disclosed in the application as coding the claimed fusion protein. Page 5, description of Figure 4. The application indicates that the vector is a modified (by insertion of the coding sequence for the fusion protein) form of the pCMVII plasmid. Id, and page 26. It is noted that SEQ ID NO: 6 has attached a human plasminogen activator (tpa) leader sequence, and an Ala-Ser linker, to the N-terminus of the chimeric protein. The claims therefore read on vectors comprising a pCMVII plasmid modified to encode the previously described HBV/HCV chimer, and variants of at least 80% identity thereto.

The teachings of the references other than Selby, Chapman, and Hartikka have been described above. They teach sequences encoding a fusion protein of the HCV E2 protein and the HBV HBsAg protein. Further, they teach the use of such coding vectors for the induction of an immune response against HCV. The references do not teach a vector of, or with at least 80% identity with, SEQ ID NO:. 6.

Selby describes the pCMVII plasmid. Column 3 lines 54-60, and Col. 15 lines 56-62. Selby describes the plasmid as being derived from another plasmid, which includes a tpa leader sequence, and a CMV promoter enhancer element (including intron A), and a bovine growth hormone terminator, and was described for the use of producing viral antigens in mammalian cells. Selby, col. 15 (describes use of portions of pCMV6); Chapman, page 3980. The Chapman reference, teaching the pCMV6 plasmid from which pCMVII was derived, also teaches that intron A of the CMV enhancer/promoter sequence results in increased protein expression. Page 3984. Chapman additionally teaches the use of the human tpa leader sequence, with an Ala-Ser linker, for the expression of viral polypeptides. Id. Thus, Selby teaches the making of the pCMVII plasmid, and both references provide teachings indicating that the pCMVII and pCMV6 plasmids would be useful for the expression of heterologous proteins in mammalian cells.

From the combined teachings of Selby and Chapman, it would have been obvious to those in the art to use of pCMVII plasmid for the expression of the HBV/HCV chimer suggested by the previously cited references. This is because the art indicates that the inclusion of the CMV expression control sequences was beneficial to the protein expression. Although the pCMVII plasmid of Selby is different from that of pCMV6, the reference indicates that it was created to include the expression control sequences of pCMV6. Thus, those in the art would have had a

reasonable expectation of success in the use of the pCMVII plasmid as a functional equivalent to the pCMV6 plasmid.

Further, those in the art would also have had a reasonable expectation of success in the use of the plasmid in an immunogenic composition in view of the teachings of Hartikka. This is due to Hartikka's teachings regarding the use of plasmids with the same control sequences as the pCMVII vector for protein expression in mammals (see e.g., page 1209, Fig. 2), and suggestions for the use of such vectors in genetic vaccines (Page 1215).

Thus, the Jacobs etc. references teach the described HBC/HCV chimer, and suggest the use of nucleic acids encoding such for genetic vaccination; whereas the teachings of Selby, Chapman, and Hartikka teach the pCMVII plasmid, and provide teachings indicating that the plasmid would be useful for protein expression in mammalian cells, and in genetic immunization. From these teachings, it would have been obvious to those in the art to use the pCMVII plasmid for the expression of the chimer suggested by Jacobs etc. Because such a construction would result in a sequence varying from SEQ ID NO: 6 by less than 80% (having only the differences identified with respect to claim 37 above), the combination of the cited references renders the claimed invention obvious.

Conclusion

17. No claims are allowed.

18. It is noted that certain of the application claims read on a genus of inventions covering nucleic acids encoding residues 384-661 of an HCV-1 polypeptide or "the corresponding residues of other HCV isolates." It is also noted that the present application provides only a

single example of such a sequence- the HCV-1 sequence of Figure 4. However, the teachings of Simmonds et al., (J Clin Microbiol 31: 1493-1503) and of Jackson et al. (J Med Virol 51: 67-79) indicate that many different HCV E2 polypeptide sequences were known in the art at the time the present application was filed. Additionally, the art indicates that the HCV E2 proteins contained epitopes within the regions of the E2 protein encoded by the claimed inventions. See e.g., Jackson, page 70, Table II, showing epitopes of various HCV isolates with the N-terminus of the E2 protein. In view of these teachings, and in view of the teachings of the application, the claims are considered to meet the written description requirement for the quoted claim limitation.

19. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> WO 96/04301, of record in the November 2003 IDS. This reference teaches that the HCV E2 protein begins at amino acid 384 or 385 of the polyprotein. See also, U.S. 5,942,234, column 3, teaching that the E2 protein begins at residue 384 of the polyprotein. Because these references indicate that the mature E2 protein begins at residue 384, it would have been obvious to those in the art to construct nucleic acids encoding chimeric proteins wherein the E2 portion begins at this residue. The teachings of these references are therefore considered relevant, but are redundant to the teachings of Michalak in view of the scope of the present claims.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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